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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/785,514	02/16/2001	Jian-Bing Fan	A-68970-1/DJB/RMS/DCF	5362

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David A. Gay
MCDERMOTT, WILL & EMERY
4370 La Jolla Village Drive
Ste 700
San Diego, CA 92122

EXAMINER	
FORMAN, BETTY J	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 09/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/785,514	FAN ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-18,21-32 and 34-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-18 21-32 34-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12 April 2006 has been entered.

Status of the Claims

2. This action is in response to papers filed 12 July 2006 in which claims 21, 23, 24, 26, 34-37 were amended and Claim 33 was canceled. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 18 October 2005 are withdrawn in view of the amendments and Applicant's comments on pages 11-12 of the Response. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection are discussed.

Claims 14-18, 21-32, 34-39 are under prosecution.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 14-18, 23, 25, 30-32 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Drmanac et al (EP 0392546, published 17 October 1990).

Regarding Claim 14, Drmanac et al disclose a method comprising providing an array composition comprising a substrate having discrete sites (i.e. HA, hybridization areas) and a population of microspheres (DP, discrete particles) containing first and second subpopulations wherein the microspheres of each subpopulation comprises a plurality of different and covalently attached target analytes (e.g. 10 ON, oligonucleotides/DP) and wherein the microspheres are distributed on the surface (Column 7, line 22-Column 8, line 29 and Column 12). The method further comprising contacting the array with a first set of read out probes (ONP, oligonucleotide probes) to detect the presence of a first target analyte (Column 18-21). Drmanac et al also teach the method wherein the hybridization pattern differences are compared between different individuals (Claim 8) and hence they disclose subpopulations from different individuals as claimed.

Regarding Claim 15, Drmanac et al disclose the method further comprising contacting the array composition with a second set of readout probes (Column 18, line 45-Column 19, line 12).

Regarding Claim 16, Drmanac et al disclose the method wherein the microspheres are randomly distributed on the surface (i.e. "mixed together and spread", Column 7, lines 25-29 and Claim 2).

Regarding Claim 17, Drmanac et al disclose the method wherein the first set of readout probes comprises at least first and second probes wherein the first and second probes are differentially labeled (Column 7, line 45-Column 8, line 29 and Column 19-20).

Regarding Claim 18, Drmanac et al disclose the method further comprising detecting the first label as an indication of the first target analyte (Column 18, lines 45-58).

Regarding Claim 23, Drmanac et al disclose a method comprising providing an array composition comprising a substrate having discrete sites (i.e. HA, hybridization areas) and a population of microspheres (DP, discrete particles) containing first and second subpopulations wherein the microspheres of each subpopulation comprises a plurality of different and covalently attached nucleic acids molecules (e.g. 10 ON, oligonucleotides/DP) and wherein the microspheres are distributed on the surface (Column 7, line 22-Column 8, line 29 and Column 12). The method further comprising contacting the array with a first set of read out probes (ONP, oligonucleotide probes) to determine the nucleotide at a detection position (sequence, Column 18-21 and Claims 1-11). Drmanac et al also teach the method wherein the hybridization pattern differences are compared between different individuals (Claim 8) and hence they disclose subpopulations from different individuals as claimed.

Regarding Claim 25, Drmanac et al disclose the method wherein the readout probe comprises a detectable label (Columns 19-20).

Regarding Claim 30, Drmanac et al disclose the method wherein the targets are target sequences (Abstract).

Regarding Claim 31, Drmanac et al disclose the method wherein the targets are nucleic acid sequences (Abstract).

Regarding Claims 32 and 34, Drmanac et al disclose the method wherein the nucleic acid sequences are genomic DNA (Abstract).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 35 and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drmanac et al (EP 0392546, published 17 October 1990) in view of Dower et al (ups 5,639,603, issued 17 June 1997).

Regarding Claim 35, Drmanac et al disclose a method of genotyping (Claim 8) comprising providing an array composition comprising a substrate having discrete sites (i.e. HA, hybridization areas) and a population of microspheres (DP, discrete particles) containing first and second subpopulations wherein the microspheres of each subpopulation comprises a plurality of different target analytes (e.g. 10 ON, oligonucleotides/DP) and wherein the microspheres are distributed on the surface (Column 7, line 22-Column 8, line 29 and Column 12). The method further comprising contacting the array with a first set of read out probes (ONP, oligonucleotide probes) to detect the presence of a first target analyte (Column 18-21). Drmanac et al also teach the method wherein the hybridization pattern differences are compared between different individuals (Claim 8) and hence they disclose subpopulations from different individuals as claimed.

Drmanac et al teach the method wherein the nucleic acid targets are linked to the microspheres but they do not teach the linkage is via receptor-ligand interaction. However, receptor-ligand linkage of nucleic acids to microspheres was well known and routinely practiced in the art at the time the claimed invention was made as taught by Dower et al.

Dower et al teach a method of wherein the sequence to be analyzed is purified via biotinylation of the sequence and receptor/ligand capture onto streptavidin coated beads (Column 21, lines 23-27 and Column 48, lines 10-19). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the receptor-ligand immobilization of Dower et al to the bead immobilization of Drmanac. One of ordinary skill in the art would have been motivated to do so based on the well known and preferred

method of sequence purification prior to analysis as taught by Dower et al (Column 21, lines 23-27 and Column 48, lines 10-19).

Regarding Claim 37, Drmanac et al disclose a method of genotyping (Claim 8) comprising providing an array composition comprising a substrate having discrete sites (i.e. HA, hybridization areas) and a population of microspheres (DP, discrete particles) containing first and second subpopulations wherein the microspheres of each subpopulation comprises a plurality of different target analytes (e.g. 10 ON, oligonucleotides/DP) and wherein the microspheres are distributed on the surface (Column 7, line 22-Column 8, line 29 and Column 12). The method further comprising contacting the array with a first set of read out probes (ONP, oligonucleotide probes) to determine the nucleotide at a detection position (sequence, Column 18-21 and Claims 1-11).

Drmanac et al teach the method wherein the nucleic acid targets are linked to the microspheres but they do not teach the linkage is via receptor-ligand interaction. However, receptor-ligand linkage of nucleic acids to microspheres was well known and routinely practiced in the art at the time the claimed invention was made as taught by Dower et al.

Dower et al teach a method of wherein the sequence to be analyzed is purified via biotinylation of the sequence and receptor/ligand capture onto streptavidin coated beads (Column 21, lines 23-27 and Column 48, lines 10-19). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the receptor-ligand immobilization of Dower et al to the bead immobilization of Drmanac. One of ordinary skill in the art would have been motivated to do so based on the well known and preferred method of sequence purification prior to analysis as taught by Dower et al (Column 21, lines 23-27 and Column 48, lines 10-19).

Regarding Claims 38-39 Dower et al teach the preferred receptor-ligand capture comprises biotinylation of the sequence and receptor/ligand capture onto streptavidin coated beads (Column 21, lines 23-27 and Column 48, lines 10-19).

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 14-18, 21-32, 34-39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-36of U.S. Patent No. 6,913,884 in view of Drmanac et al (EP 0392546, published 17 October 1990). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to method comprising immobilization of multiple targets onto one solid support, contacting with labeled probes/primers and detecting signals to analyze to immobilized targets. The claim sets differ in that the instant claims define the solid support as a microsphere. However, the patent defines the patented solid support as a microsphere e.g. Column 11, lines 13-17). Furthermore Drmanac et al teach immobilization onto microspheres whereby the need to address sample onto a support is eliminated thereby reducing the robotic component and allows miniaturization of the entire method from a level of industrial installation to the level of laboratory instruments (Abstract). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the microspheres of Drmanac to the patent solid support. One of ordinary skill in the art

would have been motivated to do so for the expected benefit of eliminating the need to address samples onto a support, reducing the robotic component of the method and allowing miniaturization of the entire method from a level of industrial installation to the level of laboratory instruments (Drmanac, Abstract).

Conclusion

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
September 12, 2006